HSCB Service Notification for the managed entry of new medicines and technologies

1.	**Treatment & Condition** Encorafenib with binimetinib for unresectable or metastatic BRAF V600 mutation-positive melanoma.
2.	**Associated appraisal body *&* Summary of ruling** NICE Technology Appraisal guidance TA562 (February 2019) Encorafenib with binimetinib is recommended, within its marketing authorisation, as an option for treating unresectable or metastatic BRAF V600 mutation-positive melanoma in adults. It is recommended only if the company provides encorafenib and binimetinib according to the commercial arrangements.
3.	**Number of people in Northern Ireland expected to take up service/therapy** NICE has not provided an indication of the number of patients expected to be treated per annum. This is because the technology is an option alongside current standard treatment options and the population size is small. It is the view of local clinicians that as this is further treatment option for this cohort of patients, 2-3 patients in NI may expect to be treated with this regimen. However clinical practice may change over time.
4.	**Patient Access Scheme Availability** (**Yes**/No) The company (Pierre Fabre) has a commercial arrangement. This makes encorafenib and binimetinib available to the NHS with a discount. The size of these discounts is commercial in confidence.
5.	**Infrastructure Requirements** Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process
6.	**Expected implementation period** There is no impediment to immediate implementation for new patients.
7.	**Commissioning arrangements** This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.

8.	**Monitoring arrangements** The HSCB cost per case process will generate quarterly reports on the number of applications. HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units. The monitoring pro forma will be adapted to capture information in respect of this regimen and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team
9.	**DoH (NI) Legislative/Policy Caveats** This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case. The Rural Needs Act (NI) 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the Act.